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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,122	01/26/2006	Tuo Jin	691-C-PCT(CN)-US	4284

7590 07/27/2007
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,122	JIN ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/2/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because Figures 11-12 do not have a legend. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 5, 9, 13, 18 and 19 are objected to because of the following informalities: Claims 5 and 13 recite the terms, “is ranged”. This should be replaced by the terms, “are in the range of”. In claim 9 the term “complimentary” should be replaced by the term “complementary”. In

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claim 18(d) the term "slat" should be replaced by the term "salt".. Claim 19 recites notations for some polymers. The expansion for the said notations should be recited followed by the notations within parentheses at the first occurrence of the terms. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 15 of U.S. Patent No. 6,998,393 ('393). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 2-8 and 11 are drawn to compositions comprising polysaccharides as the dispersed phase of an emulsion and encapsulating agents. These imitations are also seen in the compositions of claims 1-5 of '393.

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Instant claims 1 and 16 are drawn to methods of encapsulating agents. Claims 6 and 15 of '393 are also drawn to the same method.

It would be obvious to one of ordinary skill in the art at the time the invention was made that instant claims 1-8, 11 and 16 and claims 1-6 and 15 of the '393 patent are substantially overlapping.

One of skill in the art would be motivated to make compositions as instantly claimed via the methods as instantly claimed since they are similar to those of the '393 patent and would expect them to work. Similarity in structure and function and process steps entails motivation for making.

Claims 1-3, 6-12 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,805,879 ('879). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 1-3, 6-12 and 15 are drawn methods of encapsulating agents and compositions comprising polysaccharides as the dispersed phase of an emulsion and encapsulating agents. Claims 1-9 are also drawn to such compositions and method steps.

It would be obvious to one of ordinary skill in the art at the time the invention was made that instant claims 1-3, 6-12 and 15 and claims 1-9 of the '879 patent are substantially overlapping.

One of skill in the art would be motivated to make compositions as instantly claimed via the methods as instantly claimed since they are similar to those of the '879 patent and would

expect them to work. Similarity in structure and function and process steps entails motivation for making.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of encapsulation and composition comprising dextran chitosan and alginate, does not reasonably provide enablement for all polysaccharides, polymers and small molecular salts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The amount of direction provided by the inventor
- (D) The existence of working examples
- (E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

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The breadth of the claims

Claims 1 and 18 are drawn to a method for encapsulation of agents and polysaccharides respectively. The terms, agents and polysaccharide are broad and encompass several sugars and agents that fall under the definition of the term. Claim 2 is drawn to a composition that includes any component(s) as the recited phases. The term biologically active agent, protecting agents, surface modifier, aqueous polymers and biodegradable polymers recited in claims 6,3, 2, 11 and 18 are also broad.

The state of the prior art

The examiner notes that, Cleland et al (Pharmaceutical Research, 1996, 13(10), 1464-1475; document # 9 in IDS of 12/2/2004) mentions dextran and carboxymethylcellulose. However these two compounds alone are not representative of the entire class of polysaccharides as instantly claimed.

The level of predictability in the art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427.2d 833, 166 USPQ (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one of skill in the art cannot fully visualize or recognize the identity of the members of the genus. In the absence of fully recognizing the identity of the members of the genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having the claimed functional herein. Goodman and Gilman's "The Pharmacological Basis of Therapeutics", 10th Ed., 1996, page 54, teaches that the frequency of significant

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beneficial or adverse drug interactions is unknown (bottom of the left column at page 54).

Relatively small changes in the drug level can have significant adverse consequences. In the instant case one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with the many combinations of any compounds having the functional properties in the combinations claimed herein. Thus, the teachings of Gillman and Goodman clearly support that the instantly claimed invention is highly unpredictable.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the methods and compositions claimed. In the instant case the terms agents, biologically active agents, salts and polymers recited in the instant claim is purely a functional distinction that reads on any known or unknown compounds that fit the definition or might have the recited functions. The specification refers to proteins as an example of biological agent.

The existence of working examples

The working examples set forth in the instant specification are drawn to dextran and alginate in particular. Despite these examples there is little enabling disclosure for the entire class of polysaccharides, salts, polymers, etc.,. Applicant is therefore not entitled to everything that is encompassed by the broad terms recited in the instant claims..

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the method of encapsulation and compositions as instantly claimed. One of

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ordinary skill in the art would have to carry out the process in order to determine if a composition as instantly claimed can be extended to all polysaccharides, biodegradable polymers, agents, salts, etc., with regard to compatibility.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term agents and delicate agents. It is not clear what all are encompassed by these broad recitations. The specification refers to proteins as one of the biological agents. It is not clear if applicants intend only proteins as agents. In the absence of a definition any substance/chemical is considered an agent. It is also not clear if applicants distinguish between the terms "agent" and "delicate agent(s)". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte*

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Hall, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation agents, and the claim also recites delicate agents which is the narrower statement of the range/limitation. Claim 6 also recites the term biological agents, which is broad.

Claims 3-4 recite the term derivatives. In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the derivatives of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of the said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated or defined in the specification. Claim 4 also recites the terms all types of poly sugars. It is not clear what applicants intend by these terms. The metes and bounds of the recitation are unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the

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broad recitation polysugars, and the claim also recites specific polysaccharides which is the narrower statement of the range/limitation. Claim 4 recites the limitation "oligosugars" in claim 3. Claim 3 is drawn to polysaccharide. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites DNA/RNA. It is not clear if a mixture of the two or a hybrid is intended.

Claim 8 recites interferon and β followed by a comma. It is not clear what applicants intend by reciting just the Greek symbol beta. The claim also recites other therapeutic proteins and peptides. The metes and bounds of the recitation are unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation proteins and peptides, and the claim also recites specific proteins and peptides which is the narrower statement of the range/limitation.

The term "small" in claim 9 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is drawn to a composition and further recites dispersed during successive steps. The intent of this recitation is unclear.

Claim 15 recites other polymers. The metes and bounds of the recitation are unclear. The claim is rendered indefinite

Claim 18(c) recites the terms small molecular salts. The metes and bounds of the recitation are unclear. The claim is rendered indefinite. The term "small" is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 19 recites the broad recitation

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other polymers, and the claim also recites specific polymers which is the narrower statement of the range/limitation.

Claims that depend from rejected base claims that are unclear or indefinite are also rendered unclear or indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Berthold et al (Journal of Controlled Release, 1996, 39, 17-25; document #29 in IDS of 12/2/2004).

Berthold et al teach chitosan microspheres (polysaccharide particles) having size below 5 micrometers (page 18, left column, third full paragraph; right column, section 2.3). This disclosure of Berthold et al is seen to meet the limitations of instant claim 17.

Claim 17 is a product-by-process claim, which is a product claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Conclusion

Claims 1-20 are rejected.

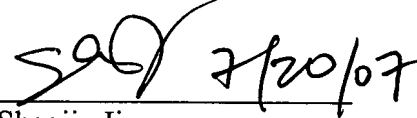
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654.

The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623